

## REMARKS

The Office Action dated July 9, 2003, has been received and reviewed. Claims 25-26 and 29-32 are pending in the present application. Claims 25-26 and 28 stand rejected in the Office Action. Applicants have cancelled Claim 28 and added Claims 29-32. Applicants respectfully request reconsideration of the application in view of the arguments below.

### I. Claim Amendments

Claim 25 has been amended to include the recitations of dependent Claim 28, which was subsequently canceled. Claims 29-32 have been added. Support for these claims can be found throughout the specification and figures, particularly on pages 2-4 of the present specification.

### II. Rejections under 35 U.S.C. § 102(b)

Claims 25 and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Kaken Pharm CO. Ltd. (JP 10279483) (hereinafter "Kaken"). Applicants respectfully traverse this rejection for the reasons set forth below.

Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000).

Applicants have amended Claim 25 to include the recitations of Claim 28 thus mooted this rejection as the Office Action did not reject Claim 28, which is dependent from Claim 25. under 35 U.S.C. § 102(b). Applicants further note that Kaken does not demonstrate a pharmaceutical formulation comprising 17 $\beta$ -estradiol or a mixture consisting essentially of salts of conjugated estrone, conjugated equilin, conjugated  $\Delta^{8,9}$ -dehydroestrone, conjugated 17 $\alpha$ -estradiol, conjugated 17 $\beta$ -dihydroequilin, conjugated 17 $\alpha$ -dihydroequilin, conjugated 17 $\beta$ -estradiol, conjugated equilinenin, conjugated 17 $\alpha$ -dihydroequilenin, and conjugated 17 $\beta$ -dihydroequilenin as recited in new Claims 30 and 32. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejection to the claims.

### III. Rejections under 35 U.S.C. § 103(a)

Claim 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaken in view of Bikle et al. Applicants have amended Claim 25 to include the recitations of Claim 28 and hence traverse this rejection for the amended claims for the reasons set forth below.

To establish a prima facie case of obviousness, the prior art reference or references when combined must teach or suggest *all* the recitations of the claim, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). To support combining references, evidence of a suggestion, teaching, or motivation to combine must be clear and particular, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Court of Appeals for the Federal Circuit has also stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). Furthermore, as recently affirmed by the Court of Appeals for the Federal Circuit in *In re Sang-su Lee*, a factual question of motivation is material to patentability, **and cannot be resolved on subjective belief and unknown authority**. See *In re Sang-su Lee*, 277 F.3d 1338 (Fed. Cir. 2002). Respectfully, as will be discussed below, the Official Action fails to meet the requirements for a prima facie showing of obviousness under § 103.

The Office Action alleges that Bikle et al. teaches that progestins are frequently used in combination with estrogen to prevent or treat postmenopausal osteoporosis. Applicants submit that there is no motivation to produce the pharmaceutical formulation as recited in independent Claim 25. Applicants submit that they are the first to discover the beneficial effects of using a non-aromatizing androgen with an estrogenic compound. Applicants point out the Examples of the present specification illustrating the fact that estradiol plus oxandrolone does not provide an additive effect and instead provides a reductive effect which shows that this combination is useful in treating hormonal deficiencies in women. There is nothing in Bikle et al. which would make the present invention obvious. Applicants further submit that Bikle et al. and Kaken fail to

In re: Leonard et al.  
Serial No.: 10/029,424  
Filed: December 20, 2001  
Page 6 of 6

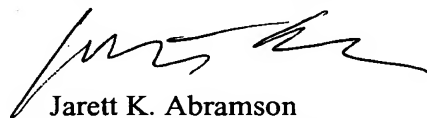
contain any motivation to combine their teachings as required by *In re Sang-su Lee*. Accordingly, Applicants respectfully request reconsideration of Claims 1-10.

### CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,



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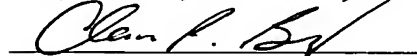
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